REMARKS

Claims 1-3, 5-10, 17-20, 23, 24, 27, and 28 are pending in the present application. Claim 5 has been amended to change its dependency from previously canceled claim 4 to allowed claim 1. Claim 18 has been amended to recite the glutamic acid decarboxylase GAD65 and the islet cell antigen IA2, consistent with the language in allowed claim 1. Applicant asserts that these amendments do not constitute new matter, and thus, their entry is requested.

Examiner's Withdrawal of Previous Rejections and Species Election Requirement

In the December 2, 2002 Office Action, the Examiner stated that all previous rejections and the species election requirement have been withdrawn.

Applicant acknowledges and appreciates these withdrawals.

Previously Proposed Drawing Corrections

The Examiner acknowledged the amended drawings submitted by the Applicant in a paper filed May 22, 1998. The Examiner stated that handwritten corrections such as those submitted are improper and will not be formally permitted. The Examiner moreover stated that "Applicant is advised that the change of 'Sfg I' to 'Sgf I' in the corrections of Figure 1 will not be allowed."

Applicant respectfully points out to the Examiner that no such correction was proposed by the Applicant. Accordingly, Applicant seeks the Examiner's clarification of this statement.

The Examiner also indicated that new corrected drawings must be filed with the changes incorporated therein and directed the Applicant to "[s]ee the PTO Form 948, mailed 8/04/99." The Examiner also indicated that Applicant must submit acceptable corrected drawings within the time period set in the Office Action.

Applicant's file contains only one Form PTO-948, dated April 30, 1998, which indicates that the drawings filed on January 29, 1998 were "not objected to by the Draftperson." A copy of this form is attached. Accordingly, it is Applicant's understanding that no corrected formal drawings are required to be submitted in response to the December 2, 2002 Office Action. Applicant will again

address the issue of drawing corrections once the Applicant has received the clarification sought above.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 5 and 6 under 35 U.S.C. § 112, second paragraph as being indefinite. Specifically, the Examiner indicated that claim 5 is dependent on canceled claim 4.

In response, Applicant asserts that the amendment to claim 5, changing its dependency to claim 1, obviates the Examiner's rejection. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 5 and 6 under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 5, 23, and 27 under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventor had possession of the claimed invention. Specifically, the Examiner took the position that the term "affinity binding pair" as it is recited in the claims is not sufficiently described. The Examiner asserted that the term is not disclosed in the specification (and thus not defined) and that the disclosure of only one such pair (biotin-streptavidin) in the claims is insufficient to describe the entire claimed genus.

In response, Applicant respectfully traverses the Examiner's rejection. Applicant points out that the specification does indeed disclose the term "affinity binding pair," and further describes how such a pair would operate to enable the binding of the fusion protein to the solid phase, in contrast, for example, to binding by direct adsorption. (See specification at page 6).

Moreover, Applicant asserts that additional affinity binding pairs would be known to one of ordinary skill in the art. Such pairs include, for example, glutathione S-transferase–glutathione, (as disclosed in Smith, et al., Single-step purification of polypeptides expressed in *Escherichia coli* as fusions with glutathione S-transferase, Gene, 67(1):31-40, July 15, 1988), and maltose binding

protein–amylase (as disclosed in di Guan, et al., Vectors that facilitate the expression and purification of foreign peptides in *Escherichia coli* by fusion to maltose-binding protein, Gene, 67(1):21-30, July 15, 1988). Applicant will submit copies of these references if so requested by the Examiner.

In light of these remarks, Applicant asserts that claims 5, 23, and 27 fully meet the written description requirement of 35 U.S.C. § 112, and thus respectfully requests that the rejection of these claims be reconsidered and withdrawn.

The Examiner rejected claims 18-20 and 27-28 under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventor had possession of the claimed invention. Specifically, the Examiner indicated that the specification does not support claims to generic "glutamic acid decarboxylase" or "islet cell antigen" as recited in claim 18, but rather only to the more specific GAD65 and IA2.

In response, without conceding the correctness of the Examiner's position, but to advance prosecution of the subject application, Applicant has amended claim 18 to include reference to GAD65 and IA2, making the language consistent with claim 1 which has been deemed allowable by the Examiner.

The Examiner also asserted that claim 19's recitation of a label that is "radioactive or fluorescent" is likewise unsupported by the specification, in that only lanthanide labels are disclosed.

In response, Applicant respectfully traverses this ground of the Examiner's rejection. Applicant points out that although lanthanide labels are indicated to be preferable, the specification does in fact recite that any suitable label can be used. In that regard, Applicant asserts that one of ordinary skill in the art would recognize that the recited lanthanide labels are merely exemplary of the various types of suitable labels that could be employed in accordance with the invention. For example, page 12, lines 5-8 of the specification indicate that a radiolabel, while less preferable than a lanthanide label, is in fact suitable for use in the claimed invention. Accordingly, Applicant asserts

that claims 18-20 and 27-28 fully meet the written description requirement of 35 U.S.C. § 112, and thus Applicant respectfully requests that the rejection of these claims be reconsidered and withdrawn.

Allowed of Claims

Applicant acknowledges and appreciates Examiner's allowance of claims 1-3, 7-10, and 17.

Objection to Claim 24

The Examiner objected to claim 24 as being dependent on rejected claim 23.

In response, Applicant asserts that the remarks set forth herein have overcome the Examiner's rejection of claim 23, thus removing the basis for the Examiner's objection to claim 24.

In view of the above amendments and remarks, it is believed that the claims satisfy the requirements of the patent statutes and fully address the Examiner's concerns as set forth in the December 2, 2002 Office Action. Accordingly, reconsideration of the instant application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

RESPECTFULLY SUBMITTED,			
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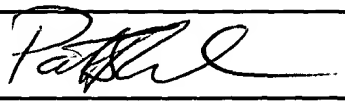
SIGNATURE		*DATE*	March 3, 2003

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Attachments: Marked-up Copy of Amended Claims
Copy of previously issued Form PTO-948

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Marked-Up Copy of the Amended Claims

5. (Amended) The fusion protein according to claim [4]1, wherein said linker peptide is provided with a member of an affinity binding pair so as to enable the binding of said fusion protein to the solid phase.

18. (Amended) A fusion protein presenting epitopes of at least two autoantigens selected from the group consisting of glutamic acid decarboxylase (GAD65), islet cell antigen (IA2), and preproinsulin, wherein said fusion protein comprises a label and a linker peptide wherein said linker peptide is selected from the group consisting of KKKRPRKKK (SEQ ID NO:2) and KKKRSRKKK (SEQ ID NO:4).